

State/Territory: FLORIDA

STANDARDS FOR THE COVERAGE OF ORGAN TRANSPLANT SERVICES

For children under age 21, Florida covers organ transplants that are medically necessary and appropriate. For recipients age 21 and older, Florida covers kidney, liver, cornea, heart and bone marrow transplants that are medically necessary. An exception is that Medicaid covered emergency services for undocumented aliens, illegal aliens and legal non-immigrants do not include care and services related to organ transplant procedures. An adult heart transplant procedure requires prior-authorization. Other transplant procedures performed at approved transplant hospitals in Florida do not require prior authorization from the Medicaid office. All out-of-state transplants and evaluations require prior authorization.

Prior authorization is requested using the Florida Medicaid Authorization Request Form to which must be attached documentation by the transplant team, indicating that the recipient is a suitable transplant candidate. The medical consultants within the Medicaid office base their determination regarding prior authorization on the recommendation made by the transplant team, and documentation submitted. Each transplant team maintains its own criteria for determining whether an eligible Medicaid recipient may be considered for suitability as a transplant candidate.

Organ transplants for Florida Medicaid recipients are restricted to organ transplant hospitals that meet Medicare participation requirements of 42 CFR 440.10 and 482 and are approved by the Director of the Agency for Health Care Administration (AHCA) upon the recommendation of the Organ Transplant Advisory Council (FS 381.0602) as a designated Medicaid transplant facility. The Organ Transplant Advisory Council and AHCA approve the standards by which the transplant hospitals are evaluated and selected. These standards, which specify the qualifications of the facility and medical staff for each approved transplant hospital, are provided in Attachment 3.1-E, Supplement I.

Post transplant services are payable as long as they are medically necessary, covered under Medicaid and included in the State Plan. Coverage for post-transplant services begins once the transplant recipient has been discharged from the inpatient hospital. Post transplant services include any medically necessary physician, outpatient, inpatient, laboratory, pharmacy and radiology services. All other program limitations apply.

ORGAN-TISSUE TRANSPLANTATION STANDARDS

INTRODUCTION

In accordance with legislative proviso language established in 1985, the Organ Transplant Advisory Council to the Agency for Health Care Administration has formulated the following standards and guidelines relative to organ transplantation.

The transplant hospitals must be hospitals or parts of hospitals that meet the requirements for participation in Medicare as a hospital per 42 CFR 440.10 and 482.

Funding of programs within the hospitals is to be restricted to those organ transplants currently considered as accepted therapeutic modalities in this state and are not to include experimental procedures. Transplantation of heart, lungs, kidneys, liver, kidney/pancreas, intestine and bone marrow are considered established procedures. The status of procedures will be periodically reviewed by the Organ Transplant Advisory Council for new recommendations.

The hospitals providing transplants must have the resources to provide pre-transplantation management of the patient undergoing failure of an organ and have continued patient follow-up by appropriate specialty services.

In the following sections recommended guidelines for general operation of transplant hospitals and for transplant programs will be described.

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**END-STAGE DISEASE AND ORGAN-TISSUE TRANSPLANTATION HOSPITALS
REQUIREMENTS**

The hospital must:

1. Have programs for transplantation of a minimum of two major organs. The following transplants are considered therapeutic procedures: heart, lungs, kidney, liver and bone marrow. Other transplants including pancreas, liver-bowel, and neural tissue are still considered experimental. Skin, bone and corneal transplants are not to be accepted as a requisite program for establishing a transplant hospital.
2. Function under an integrated institutional and administrative structure.
3. Have the staff and resources necessary for care of the patient's chronic illness prior to transplantation, during transplantation and in the postoperative period. Services and facilities for in-patient and out-patient care must be available.
4. Utilize common resources (laboratories, special clinical facilities, etc.) for all transplantations.
5. Share services of professional staff as appropriate.
6. Have a staff of physicians in the following specialities with expertise in caring for patients with end-stage disease requiring transplantation.
 - a) vascular surgery and/or pediatric vascular surgery
 - b) cardiology and/or pediatric cardiology
 - c) neurology
 - d) anesthesiology with experience with neonatal/pediatric cardiac surgery
 - e) infectious disease and/or pediatric infectious disease
 - f) radiology - angiography with experience with neonatal/pediatric cardiac surgery
 - g) neurosurgery
 - h) orthopedics
 - i) urology
 - j) endocrinology
 - k) pathology

- l) nephrology and/or pediatric nephrology
 - m) genetics
 - n) pulmonology/inhalation therapy and/or pediatric pulmonology
 - o) gastroenterology and/or pediatric gastroenterology
 - p) immunology and/or pediatric immunology
 - q) hematology-oncology and/or pediatric hematology
 - r) psychiatry
 - s) intensive care and/or pediatric intensivists
 - t) nuclear medicine
 - u) neonatology
7. Have additional required personnel including:
- a) Nurses, nurse practitioners or physicians assistants skilled in the care of adult or pediatric patients with end-stage disease and transplants and experienced in working with chronically ill patients and their families.
 - b) Social workers, psychologists and other individuals skilled in performing comprehensive psychological assessment and counseling adult or pediatric patients and families of patients.
 - c) Consultants who are experts in blood banking and capable of meeting the unique needs of transplant patients on a long term basis.
 - d) Experienced pastoral professionals on staff.
 - e) Legal officer within the administration who is familiar with transplantation laws and regulations.
 - f) Health educators/vocational specialists expert in the medical needs of transplant patients.
 - g) Nutritionists expert in the nutritional needs of adult and/or pediatric transplant patients.
 - h) Respiratory therapists expert in the medical needs of adult and/or pediatric transplant patients.
8. Have available within the same institution the resources of the Basic Science Departments.

9. Emphasize the common utilization of generic ancillary services for patients including rehabilitation, social services and education as well as provision of appropriate surroundings.
10. Maintain transplant hospital designation through an annual review by the Organ Transplant Advisory Council for the first three years and at appropriate intervals thereafter.
11. Operate a single transplantation program within the hospital to encompass each of the transplant specialties in order to maximize resources and avoid duplication.
12. Have established programs of research related to organ transplantation.
13. Have an institutional review board for the purpose of reviewing patient related research protocols.
14. Relate to an organized organ procurement system or systems.
15. Have available a facility for long-term economical housing for patients and families (a Ronald McDonald House as prototype).
16. Have training programs with fellowships in research and clinical medicine in disciplines related to transplantation in the hospital. The facility staff members involved in patient care in pre- and post-transplantation phases would include trainees in clinical care as well as those in research.
17. Have age appropriate Intensive Care Units which includes facilities for prolonged, reverse isolation when required.
18. Have a Clinical Review Board/Committee within each transplant hospital for review and decision making regarding the suitability of a transplant candidate. This review process must be completed prior to Agency for Health Care Administration (AHCA) approval of funding for the transplantation.
19. Develop and provide on-going education programs for patients, their families and the patient's primary care physician regarding transplantation care.
20. Develop and provide training and education programs to update transplantation information for community providers, including physicians and nurses.
21. Develop and maintain current written protocols for patient care within each transplant hospital, including logistics for patient management and evaluation during the prehospital, in-hospital and immediate post-discharge phases.
22. Have detailed plans for therapeutic and evaluative procedures for the acute and long term management for each transplant patient, including commonly encountered complications.

23. Have written plans for cost containment.
24. Establish and provide a data base for review of success and failure rates, morbidity and mortality rates, and critical assessment of transplant management for each type of transplant. The data will include: surgical complications, rate and type of graft survival, patient survival and patient in-hospital days for the first six months. Data should be separate for pediatric and adult patients.
25. Be designated by the Director of the Agency for Health Care Administration with recommendation from the Organ Transplant Advisory Council, in writing, specifying the approved transplantation hospitals. Such designation will be made following a site review by the Organ Transplant Advisory Council at the request of the medical facility.
26. Meet all applicable programmatic requirements for staff, facilities and services as specified within the program prior to approval of a hospital for pediatric transplantation.

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**GUIDELINES FOR THE COMPREHENSIVE LIVER FAILURE AND
TRANSPLANTATION PROGRAM**

In addition to the requirements recommended for the designation of an End-Stage Disease and Organ-Tissue Transplantation Hospital, the following guidelines are required of the Comprehensive Liver Failure and Transplantation Program.

1. Liver transplantation must be performed in a medical facility with:
 - a) A direct research interest in liver transplantation and related biology.
 - b) A pediatric and/or adult Division of Gastroenterology, as appropriate, including clinics and adequately equipped procedure rooms.
 - c) Interaction of infectious disease experts, pediatric and/or adult hematological consultants, an efficient blood bank and a major program for hepatic diseases, including congenital defects, inborn errors of metabolism and related gastrointestinal disturbances.
 - d) Age-appropriate (pediatric and/or adult) intensive care units for management of patients in the immediate postoperative period for a minimum of three days.
 - e) An age-appropriate hospital in-patient unit with support services for the transplanted patient for a minimum of three months.
 - f) A convalescent unit adjacent to the medical facility (such as the Ronald McDonald House) for further monitoring of progress for approximately one month post-hospital discharge following transplantation. Subsequent ambulatory visits would require the use of the convalescent unit on a continuing basis.
2. Service required for the support of the patient in liver failure and requiring transplantation must include:
 - a) A radiological service able to provide complex biliary procedures for both pediatric and/or adult patients as appropriate, including transhepatic cholangiography, portal venography and arteriography.
 - b) A Nuclear Medicine Service with advanced techniques to eventually include magnetic resonance for liver scanning and assessment of parenchymal viability.

- c) A laboratory to perform routine liver functions as well as required chemistry, hematology and virology tests with the capability of prompt reporting of results to in-patient and out-patient units. The support of the patient's clotting mechanisms during transplantation requires the immediate availability of pertinent test results.
 - d) Anesthesiology service with specially trained members including practical learning experience in hepatic transplantation. It is recognized that the patient is in a unique physiological state during anhepatic and revascularization surgery requiring blood replacement. Therefore, for maintenance of the patient's homeostasis during liver transplant surgery, an academic Department of Anesthesiology must designate individuals uniquely trained to provide this service. The anesthesiology service is required to continually upgrade and modify its procedures based on new and accepted techniques utilized in transplantation surgery.
- 3. Staffing based on the approved transplant hospital requirements previously listed. Program personnel must be specially trained and skilled in the care of patients with hepatic disease and liver transplantation.
 - 4. Patients considered for liver transplantation are those with end-stage hepatic disease in which death due to the disease is likely to occur within one year without transplantation.

**GUIDELINES FOR THE
BONE MARROW TRANSPLANTATION PROGRAM**

In addition to the requirements recommended for the designation of an End-Stage Disease and Organ-Tissue Transplantation Hospital, the following guidelines are required of the Bone Marrow Transplantation Program.

1. Bone marrow transplantation must be performed in a medical facility with:
 - a) A direct research interest in bone marrow transplantation and related biology, as well as provisions for the assimilation of relevant new technologies and treatment modalities.
 - b) A Hematology-Oncology-Immunology transplantation team expert in pediatric and/or adult bone marrow transplantation to provide primary care including the active coordination of services from ancillary pediatric and medical specialties including Infectious Disease, Surgery, Intensive Care, Hematopathology, and Transfusion Services.
 - c) A transplantation team which: (1) has received specialized training and experience in pediatric and/or adult bone marrow transplantation, (2) would direct the pre-transplantation care and the permanent follow-up of the transplant recipient including the maintenance of immunosuppressive therapy and the treatment of complications, (3) would be expert in aplastic anemias, immunologic diseases requiring transplantation, neoplastic diseases, including hematopoietic and lymphopoietic malignancies, and non-neoplastic disorders, i.e. storage diseases, and (4) would include an expert in blood banking who is capable of meeting the unique needs of the transplanted patient on a long term basis.
 - d) A Radiation Therapy Division which is productively interested in the evolving therapy and newest advances in bone marrow transplantation, including sub-lethal x-irradiation, bone marrow ablation and total lymphoid irradiation. Appropriate equipment must be available for the specialized needs of the patient requiring bone marrow transplantation.
 - e) A laboratory with the provision for assimilation of new techniques and therapies such as use of monoclonal antibodies, the separation of lymphocyte and hematological cell subpopulations and their removal for the prevention of graft versus host disease. Appropriate quality controls must be established for therapy.

- f) Age-appropriate in-patient transplantation units and clinical support services for a minimum of six weeks post-transplant hospitalization. Post-transplantation care must be provided in a laminar airflow room or in a private room with positive pressure and reverse isolation procedures. Intensive nursing care must be provided throughout the stay.
 - g) An age-appropriate out-patient unit for close supervision post discharge.
 - h) A convalescent unit adjacent to the medical facility (as the Ronald McDonald House or convalescent apartments) to provide temporary residence during the prolonged convalescence.
2. Staffing based on the transplant hospital requirements listed above. Program personnel must be specially trained and skilled in the care of pediatric and/or adult patients who will be candidates or recipients of bone marrow transplantation.